

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES	)	
INTERNATIONAL SRL	)	
a corporation of Barbados,	)	
	)	
Plaintiff,	)	C.A. No. 05-586-GMS
	)	C.A. No. 05-730-GMS
v.	)	C.A. No. 06-620-GMS
	)	CONSOLIDATED
ANDRX PHARMACEUTICALS, LLC	)	
and ANDRX CORPORATION	)	
	)	
Defendants.	)	

**DEFENDANTS' REPLY BRIEF IN FURTHER SUPPORT OF  
MOTION FOR LEAVE TO FILE FIRST AMENDED ANSWER,  
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

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## INTRODUCTION

Andrx's motion should be granted because Biovail does not even attempt to distinguish the weight of supporting authority cited by Andrx in its opening brief. In case after case, this District and courts around the country permit amendment to add inequitable conduct shortly after the defendant has sought to confirm the facts in key depositions to ensure compliance with Rules 9(b) and 11. These decisions squarely reject Biovail's arguments here: (a) that the defendant already had the facts by virtue of having the prosecution history or other produced documents, (b) that the defendant did not succeed in getting new facts from the witnesses in deposition, and (c) that the patentee would need discovery regarding the claim.

Unable to distinguish Andrx's authority, Biovail simply ignores it, and instead presents snippets from a hodgepodge of non-patent and patent cases in which the party seeking amendment waited until after summary judgment or the eve of trial. Biovail's cases are readily distinguishable.

Here, Andrx did not delay, much less *unduly* delay, bringing this motion. To the contrary, Andrx proceeded quickly after discharging its responsibility to seek to confirm the facts in deposition underlying its serious allegations of inequitable conduct. Andrx provided a copy of the proposed amended answer to Biovail on March 12, 2007 – barely a week after the deposition of Dr. Mamajiwallah, whom Biovail had refused to produce until ordered to do so by the Court. Indeed, Biovail refused to produce a single witness for deposition on the '866 patent until the end of fact discovery, after being ordered to do so by the Court. Biovail has only itself to blame for any inconvenience arising from the fact that it delayed producing these witnesses for depositions until (and even after) the end of fact discovery.

Biovail will not suffer any prejudice as a result of the proposed amended answer. The relevant Biovail witnesses already have been deposed. Andrx is not seeking any additional testimony, and Andrx has provided Biovail with a detailed statement of the facts and evidence supporting its claim in the expert reports of Dr. Marvin Meyer and Dr. Roland Bodmeier.

Finally, as demonstrated below, Andrx's prompt filing of this motion after deposing the key players in Biovail's prosecution of the '866 patent was entirely proper. Virtually every one of Biovail's arguments has been squarely rejected by this and other courts on the same and even less compelling facts. Under the circumstances, Andrx respectfully submits that it is entirely appropriate for the Court to consider Biovail's make-weight arguments in the larger context of the case, and the recurring theme in everything that Biovail does or says: DELAY TRIAL. Biovail knew its arguments were weak, but it made them anyway, attempting to shift the focus from the issue at hand to the October 9, 2007 trial date that Biovail time and time again has tried to push back in this Hatch Waxman Act case.

The motion should be granted.

## **ARGUMENT**

### **I. ANDRX'S MOTION IS TIMELY, AS A MATTER OF LAW.**

#### **A. Andrx's Motion Is Timely Because Andrx Filed Shortly After Deposing The Key Players In Prosecution Of The Patents During Which The Inequitable Conduct Occurred.**

This District and courts around the country hold that there is no undue delay where a defendant moves to add inequitable conduct allegations shortly after deposing the key players in the prosecution. In *Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 489 (D. Del. 2003), the defendant Digene moved to add inequitable

conduct allegations a little more than a month after confirming the facts in depositions of the inventors. Enzo opposed based on the same argument offered by Biovail in this case: that the defendant was not justified in waiting until after the depositions, because the plaintiff previously had produced the prosecution history. *Compare id.* with Biovail Br. at 7. In granting leave to amend, the Court explained that Digene's effort to confirm the facts through deposition not only was reasonable, but perhaps mandatory:

[The] Court concludes that Digene is pleading a new legal theory based on a new set of facts, which were recently confirmed by the depositions of [the inventors]. Although Enzo contends that the facts underlying the inequitable conduct were available to Digene in the public prosecution history of the '581 patent, the Court concludes that since the Rule 9(b) "pleading with particularity" requirement is implicated with regard to the inequitable conduct claim, Digene was prudent and possibly required to confirm the factual allegations through discovery.

*Id.* at 489. The Court went on to conclude that the period of a little more than a month between the depositions and Digene's motion was reasonable, and granted leave to amend. *Id.*

The court in *Advanced Cardiovascular Systems v. Scimed Life Systems*, 989 F. Supp. 1237, 1247 (N.D. Cal. 1997), likewise found no undue delay in defendant's moving to add inequitable conduct allegations shortly after attempting to confirm the facts in a deposition of a key player in the prosecution. In addition to rejecting the same prosecution history argument, the *Advanced Cardiovascular* court also rejected Biovail's argument that the defendant failed to obtain new facts from the deposition. *Compare id.* with Biovail Br. at 8. The court concluded: "[B]ecause the legal theory implicates Federal Rule of Civil Procedure 9(b), requiring pleading of fraud with particularity,

[defendant] was entitled to confirm factual allegations before amending to include the inequitable conduct defense.” *Id.*

Likewise, in *Rhone-Poulenc Argo S.A. v. Monsanto Co.*, 73 F. Supp. 2d 537 (M.D. N.C. 1997), the court granted leave to add inequitable conduct allegations shortly after defendant attempted to confirm the facts in deposition – and again rejected the same arguments offered by Biovail in this case. In so doing, the court explained that the relevant inquiry was not whether it turned out that the plaintiff RPA’s witnesses actually provided new facts in deposition beyond what was in the documents, but rather the reasonableness of defendant Monsanto’s attempt to confirm the facts through deposition.

RPA argues that those depositions did not present any new information related to the defense of inequitable conduct, and that Monsanto had the documents needed to assert the claim as early as May 1998, when RPA produced the bulk of its documents. However, RPA misconstrues the inquiry by focusing on whether material information actually was obtained at the depositions in October 1998. *The proper question is whether it was reasonable for Monsanto to expect to obtain clarifying information regarding the claim at the deposition, and therefore to wait until after the deposition to file the motion.*

*Id.* at 538-539 (emphasis added). The court went on to observe that it was reasonable because the witnesses were important fact witnesses, and that “Monsanto appropriately fulfilled its obligation to investigate its claim thoroughly prior to making it.” *Id.*<sup>1</sup>

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<sup>1</sup> *Accord Go Medical Industries PTY v. C.R. Bard, Inc.*, No. 1:93cv-1538-HTW, 1995 WL 605802, at \*4 (N.D. Ga. July 6, 1995) (Ex. A hereto) (granting motion to add inequitable conduct after depositions, explaining that “while defendant may have obtained some information to support its new allegation in September 1994, this court will not penalize defendant for obtaining additional, confirming information in January 1995 to support its claims – especially given that Rule 9(b) requires that allegations of fraud, such as inequitable conduct before the U.S. Patent Office, be stated with particularity”).



In the case at bar, Andrx provided Biovail with a copy of the inequitable conduct allegations on March 12, 2007 – which was barely one week after deposing Biovail’s Dr. Mamajiwallah on February 27, 2007, a Biovail employee involved in prosecution of the patent, and whose deposition Biovail had refused until this Court ordered Biovail to produce him. *See* Tr. of Feb. 9, 2007 Conf. at 17 (D.I. 138). After receiving the proposed allegations, Biovail delayed more than a full week, until March 20, 2007, to convey its refusal to consent. Andrx filed this motion on the very same day, March 20, 2007.

Even though Andrx cited *Enzo*, *Advanced Cardiovascular* and *Rhone-Poulenc* in its opening brief, Biovail does not even attempt to address these cases in its opposition brief. Of necessity, Biovail’s strategy appears to be to ignore them and hope that they will go away, because they are so clearly on point and compel a finding of no undue delay by Andrx in filing this motion.

**B. The Cases Cited By Biovail Are Not To The Contrary  
And Are Readily Distinguished As Inapposite To The  
Facts In This Case.**

Biovail fails to cite any authority contradicting *Enzo*, *Advanced Cardiovascular* or *Rhone-Poulenc*, and the patent cases Biovail does cite are plainly inapposite. In *Inline Connection Corp. v. AOL Time Warner Inc.*, 237 F.R.D. 361, 367-368 (D. Del. 2006), the defendant waited more than two years after the final deposition before seeking leave to assert its inequitable conduct allegations in a third amended answer. The defendant in *Remington Arms Co. v. Modern Muzzleloading*, No. 2:97 CV 00660, 1998 WL 1040949, at \*2 (M.D. N.C. Dec. 17, 1998) (Ex. B hereto), waited until after the Markman hearing and filing of summary judgment motions, which the court noted was a full three months

after the deposition of the inventor. Similarly, the defendant in *Lifescan, Inc. v. Polymer Tech. Int'l Corp.*, No. C94-672R, 1995 WL 271599 (W.D. Wash. Jan. 3, 1995) (Ex. C hereto), delayed seeking leave to amend until summary judgment motions were filed on the last day for dispositive motions.<sup>2</sup>

Biovail's non-patent authority likewise is readily distinguishable, over and above the fact that it does not deal with the question of when an alleged infringer can reasonably be expected to have sufficiently certain and specific information to plead inequitable conduct. In Biovail's cited cases, the party seeking amendment waited until after summary judgment or remand from the court of appeals with instructions to enter judgment in favor of the opposing party. *See, e.g., Toth v. Glazer*, 162 F.R.D. 549 (E.D. Wisc. 1995) (motion to amend brought after summary judgment and within six weeks of trial); *USX Corp. v. Barnhart*, 395 F.3d 161, 168 (3d Cir. 2004) (motion to amend brought after summary judgment); *Cureton v. National Collegiate Athletic Assoc.*, 252 F.3d 267, 272 (3d Cir. 2001) (motion to amend filed after summary judgment and appeal with remand instructing entry of judgment for other party).<sup>3</sup>

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<sup>2</sup> Even if the facts of *Remington* and *Lifescan* were not obviously distinguishable from the case at bar, the precedential value of these cases would be subject to considerable doubt. The only two courts that have cited *Remington* declined to follow it denying leave to amend. *See Mercexchange, LLC v. Ebay, Inc.*, 271 F. Supp. 2d 784, 786-787 (E.D. Va. 2002); *Holman v. IMC Mortgage*, No. JFM 99-1778, 2001 WL 21222 (D. Md. Jan. 9, 2001) (Ex. D hereto). No court has even cited, much less followed *Lifescan*.

<sup>3</sup> In *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993), the court affirmed denial of leave to amend a complaint by debenture holders upon a finding that the historical information at issue was known from the outset of the litigation, and that the inclusion of such information would have been futile.

## II. BIOVAIL HAS FAILED TO DEMONSTRATE ANY COGNIZABLE PREJUDICE.

Biovail is somewhat vague about the prejudice it supposedly will suffer if the motion is granted. In virtually identical circumstances, courts uniformly have rejected Biovail's suggested theories of prejudice. For instance, Biovail suggests prejudice because it is now too late for Biovail to obtain necessary discovery from Andrx with respect to the inequitable conduct allegations. Courts recognize, however, that the defendant in a patent case does not have documents or witnesses relevant to the patentee's conduct before the Patent Office. *See, e.g., Go Medical*, 1995 WL 605802, at \*4 (rejecting claim of prejudice arising from addition of inequitable conduct claim where patentee did not identify any documents or other information in defendant's possession relevant to patentee's own conduct before the Patent Office).

Biovail's suggestion of a need for contention interrogatories (Biovail Brief at 10) borders on the frivolous, because Andrx already has provided Biovail with a detailed written expert report of the alleged inequitable conduct in the reports of Dr. Roland Bodmeier and Dr. Marvin Meyer. *See* Declaration of Steven Maddox filed herewith ("Maddox Decl."), Ex. A at ¶¶ 53-80 and Ex. B, respectively. *Enzo*, 270 F. Supp. 2d at 489 (no prejudice where party seeking to add inequitable conduct has provided details concerning defense); *Rhone-Poulenc*, 73 F. Supp. 2d at 539 (same).

Even if Biovail's claimed prejudice were legally cognizable, Biovail still would not be entitled to benefit because Biovail itself created the problem by refusing to produce its witnesses until the end of fact of discovery – and until forced to do so by the Court. As the Court may recall, Andrx requested depositions of the inventors and prosecution attorney back in September 2006. *See* letter from Andrx to Court dated

12/14/06 at 2 (D.I. 114). Andrx asked for them again in October, and again in November. *Id.* Finally, Andrx sought the Court's intervention, and Biovail was ordered to produce in early 2007. *See* Order of Dec. 12, 2006 (D.I. 121). Furthermore, Andrx asked for the deposition of Dr. Mamajiwallah based on what Andrx learned in the depositions. Again, Biovail refused, and Andrx had to obtain the Court's order requiring his production. *See* Tr. of Feb. 9, 2007 Conf. at 17 (D.I. 138).

It was Biovail's decision to stonewall and delay depositions until the end of fact discovery. To the extent there are any consequences from that delay, the consequences are to be borne by Biovail, not Andrx. Surely, a patentee is not to be rewarded for refusing to produce its own witnesses until ordered to do so, and then at the end of fact discovery.<sup>4</sup>

As to Biovail's remaining prejudice arguments, Biovail fails to offer any authority for its theory of prejudice arising from the supposed burden of presenting the three previously-deposed witnesses at trial. *See* Biovail Brief at 10. Biovail asserts that these witnesses should be regarded as third-parties. As an initial matter, Andrx observes that Biovail had no trouble producing these witnesses for deposition without a subpoena, and it is difficult to credit Biovail's suggestion that it had not intended to present its inventors

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<sup>4</sup> The Court likewise should not credit Biovail's professed surprise that Andrx asserted inequitable conduct after deposing Dr. Mamajiwallah. For instance, during the conference call with the Court in which Biovail was ordered to produce Dr. Mamajiwallah, Andrx made clear that it sought the deposition in connection with certain data that had been submitted to the Patent Office. *See* Tr. Feb. 9, 2007 Conf. at 14 (D.I. 138). Further, in deposition, when Biovail's prosecuting attorney claimed not to understand what was meant by a "tension" between the data she possessed and what she told the Patent Office, Andrx removed any ambiguity by restating the question to be whether she thought whether the data did not render what she told the Patent Office to be "false and misleading." Maddox Decl., at Ex. C at 167:4-168:9.

at trial. But giving Biovail the benefit of this doubt as to the witnesses' availability and Biovail's intention not to call the inventors at trial, Biovail easily can submit their deposition testimony. After all, if Biovail really did believe that the witnesses might not be available for trial, Biovail had the same opportunity that Andrx had to obtain their testimony during the deposition.

Biovail likewise fails to support or substantiate its theory of prejudice arising from an unspecified need for additional experts for the inequitable conduct claim. *See* Biovail Brief at 10. In light of the Court's rule limiting the testimony of so-called patent law experts, the parties have agreed that neither will call such an expert with respect to inequitable conduct. Andrx's expert evidence concerning the false or misleading technical statements and contradictory data are found in the reports of Andrx's two technical experts on the '866 patent – the same two who have addressed invalidity and will address infringement. Biovail has not provided any reason to believe that the two technical experts who have served reports on infringement of the '866 cannot address the technical issues presented in the inequitable conduct allegations. Further, since Biovail has had those allegations for over almost a month before the first round of reports, and well before Biovail's opposition, Biovail's failure to provide any such reason is extremely telling.

Biovail has failed to establish any cognizable prejudice that would result from granting Andrx's timely motion to amend.

### III. BIOVAIL HAS FAILED TO MEET ITS BURDEN OF DEMONSTRATING THAT AMENDMENT WOULD BE FUTILE.

Biovail's tertiary argument is that the proposed amendment would be futile. With respect to futility, Biovail bears the burden of proving that Andrx can prove no set of facts entitling it to the relief it seeks – the same standard as applied in motions to dismiss for failure to state a claim under Rule 12(b). The gravamen of Biovail's argument is that there can be no inequitable conduct because the Examiner was given the prior art references about which Biovail's attorney and expert affiant allegedly lied to the Patent Office. That is, the Examiner should have known not to trust what Biovail's agents said, and could have found out that they were lying if he had studied the prior art references. *See Biovail Br.* at 14.

Again, this District and courts around the country have squarely rejected Biovail's arguments in granting leave to assert inequitable conduct allegations. The Court's decision in *Enzo* is directly on point. Like Andrx here, the defendant Digene "contend[ed] that the inventors of the [patent] made several misrepresentations to the PTO during prosecution of the [patent], including misrepresentations about what the inventors thought the prior art disclosed or taught." *Enzo*, 270 F. Supp. 2d at 490. In response to the same argument presented by Biovail here, this District held:

While the Court recognizes that the attempt of a patent applicant to distinguish its patent from prior art does not itself constitute a material omission or misrepresentation, the Court cannot conclude with certainty, at this juncture that Digene can "prove no set of facts in support of [its] claim which would entitle [it] to relief," given that it has alleged misrepresentations about things such as the effective filing date and mischaracterizing and withholding prior art.

*Id.*

Like the inequitable conduct allegations in *Enzo*, Andrx's inequitable conduct claim is based on far more than Biovail's mere attempt to distinguish its patent from prior art. Andrx alleges, *inter alia*: affirmative misrepresentations of what the prior art unambiguously disclosed, as opposed to merely a difference of opinion in interpretation (Am. Answer at ¶¶ 27-33); false and misleading affirmative statements in an affidavit that Biovail submitted to the PTO (*Id.* at ¶¶ 34-45); the concealment and failure to disclose contradictory experimental data (*Id.* at ¶¶ 46-50); the concealment and failure to disclose prior art (*Id.* at ¶¶ 51-57); and affirmative misrepresentations as to the operability of alternative formulations about which the Examiner had inquired (*Id.* at ¶¶ 58-63).

Not surprisingly, Biovail fails to meet its heavy burden in the conclusory four pages devoted to futility.



### CONCLUSION

For all of the foregoing reasons, the motion should be granted. Further, the Court should not accept Biovail's unsubstantiated and conclusory assertions regarding trial as a motion to yet again reconsider the trial date of October 9, 2007. As the Court is well aware, delaying trial in a Hatch Waxman Act case would be a substantial financial windfall for plaintiff due to the automatic stay provisions of the Act. To the extent that Biovail can be said to suffer any prejudice as a result of time-pressure, Biovail has only itself to blame for having refused to produce its witnesses until the end of fact discovery, and even then only after being ordered to produce them. Such obstructionist tactics should not be rewarded.

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Dated: April 11, 2007  
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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

**CERTIFICATE OF SERVICE**

I, Kenneth L. Dorsney, hereby certify that on April 11, 2007, the attached document was hand-delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

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